Prospective randomized study of the effect of autologous concentrated thrombocytes versus corticosteroid injections in lateral epicondylitis.

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Ethical review	Not approved
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29929

Source
ToetsingOnline

Brief title
Effect of autologous thrombocytes in lateral epicondylitis.

Condition

- Tendon, ligament and cartilage disorders

Synonym
lateral epicondylitis, tennis elbow

Research involving
Human

Sponsors and support

Primary sponsor: Ortomed

Source(s) of monetary or material Support: Orthomed BV

Intervention

Keyword: autologous, epicondylitis, tennis elbow, thrombocytes

Outcome measures

Primary outcome

Each patient randomly assigned to a treatment and with at least one non-missing pre- and post-baseline measurement, will be classified at each visit, as either a treatment success or failure. Patients with a painscore reduction of >25% compared to baseline, did not require pain medication beyond the protocol defined allowable amount, and did not require escape therapy will be considered a treatment success.

The absolute change from baseline to endpoint means the baseline value is subtracted from the endpoint value. Percent change is defined as the absolute change multiplied by 100 divided by the baseline value. For patients whose pain improves, these values will be less than zero.

Secondary outcome

-

Study description

Background summary

Tenniselbow, also known as lateral epicondylitis is the most common disorder of the elbow and is present in approximately 1.5% of the population at some time. The incidence is 6 per 1000 and the prevalence 7 per 1000 patients per year. More than half of the patients with lateral epicondylitis do not visit the

general practitioner. 3-6 % of the patients are send to the orthopedic surgeon.
Manual workers and racket sports athletes are at high risk.
The condition typically affects patients between 35 and 50 years old.
The exact cause of lateral epicondylitis is unknown. It is assumed that micro- and
macroscopic lesions in the common origo of wrist- and fingerextensors (COE) are involved. The lesions are usually caused by overuse of these muscles.
Histology specimens from chronic cases confirm that it is not an acute inflammatory condition, but rather a failure of the normal tendon repair mechanism associated with angiofibroblastic degeneration with deposition of glycosaminoglycane, calcification and changes in cellmorphology. Abnormal fibroblastdifferentiation has an important role in thee pathogenesis of tendinosis.

Injections of corticosteroids have been proven to decrease the pain temporarily and is the golden standard in therapy of lateral epicondylitis.
However, te condition can persist for a long period of time and/or with such intense pain that alternative treatment is indicated.
Numerous methods have been advocated for treating tenniselbow. These include rest, activity restriction, bracing, physical therapy, extracorporal shockwave therapy, non-steroidal anti-inflammatory medication, corticosteroidinjections, botulism toxininjections, acupuncture etc. However, few of the therapies rest on scientific evidence and none has been proven more effective than the others.
A new therapy is the local injection of autologous platelet concentrate obtained from a small volume of autologous blood, into the COE.
This concept expands on the work by Edwards et al [2003] where whole blood was injected into the area, and directly addresses the underlying etiology.
In previous studies it has also been proven that injection of 'Platelet Rich Plasma' (PRP) in patients with plantary fasciitis enhances repair.
The same has been proven in rats with Achilles tendonlaesions.
The PRP has a 5-8 times higher concentration of platelets compared to normal blood. Platelets play an important role in the repair of tissuedamage.
They contain several growthfactors that are essential for the repair of tissue; Platelet Derived Growth Factor, Transforming GF-ß, Insulin like GF, Vascular Endothelial GF, Epidermal GF en Fibroblast GF. These growthfactors can activate immature fibroblasts, as well as stimulate celproliferation and vascular formation.
By activating the platelets several growthfactors are released, which enhance the repair of the COE, therefore decreasing the pain.

Study objective

The objective of this study is to prove that a single injection of PRP in the COE decreases the pain and duration of the condition in patients with chronic lateral epicondylitis compared to injection with lidocaine and corticosteroids.
The specific objective is to give patients with chronic lateral epicondylitis

an alternative before opting for surgical treatment.

Study design

The study design is a prospective randomized study, where patients receive a single injection in the COE.
Patients will be randomly assigned into one of two treatment arms. The patients in the studygroup will receive an injection of buffered autologous platelet concentrate and the patients in the controlgroup will receive an injection of lidocaine and corticosteroids in identical syringes.
The study will be conducted over a period of 6 months and contain a maximum of 115 investigational cases with an equivalent number of control cases. All enrolled patients will meet the inclusion criteria. The study will continue until all study participants reach their 24-week follow-up assessment.

Study burden and risks

As with any procedure involving an injection, there are risks involved with the injection of buffered autologous platelet concentrate for treatment of lateral epicondylitis. Potential adverse events include, but are not limited to: bleeding, infection, nerve/nervous system damage, no relief of symptoms, and worsening of symptoms. Rarely, some adverse events may be fatal. These possible adverse events are not unique to the RecoverTM Kit and as stated above, may occur with any procedure involving an injection.

Potential Risks Associated with Device
Patients participating in the study may be subject to increased risks and/or adverse invents including, but not limited to:
• Pain
• Deep venous thrombosis
• Scar tissue formation
• Reaction to Bupivacaine/Epinephrine, which could involve allergic reaction, local toxicity, and potentially intravascular injection
• Thrombotic complications

Minimization of Risk
To minimize risk, the investigational plan has defined a patient population that limits exposure of the device to patients conforming to the proposed indications and inclusions/exclusions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Men and women with lateral epicondylitis > 3 months
-Pain with palpation of the lateral epicondyl
-Pain not responding to wearing a brace or manual therapy

Exclusion criteria

-Deformities of the elbow, arthrosis, previous surgery or trauma of the elbow confirmed by X-ray(AP,lateral).
-Surgical treatment or corticosteroidinjections for lateral epicondylitis in last 6 months.
-Cervical radiculopathy or carpal tunnel syndrome in medical history.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-04-2006
Enrollment:	230
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Not approved

Date:	29-01-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-002198-32-NL
CCMO	NL12360.000.06